



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,295	09/11/2003	Wolf-Ruediger Schaebitz	242650US0CONT	6092

22850 7590 05/22/2008
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MACFARLANE, STACEY NEE

ART UNIT	PAPER NUMBER
----------	--------------

1649

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

05/22/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com
oblonpat@oblon.com
jgardner@oblon.com

Office Action Summary	Application No.		Applicant(s)	
	10/659,295		SCHAEBITZ ET AL.	
	Examiner		Art Unit	
	STACEY MACFARLANE		1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9,11-14,16-19 and 105-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-7, 9, 11-14, 16-19 and 105-112 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/7/2008</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Formal Matters

1. While the Art Unit location of your application in the USPTO has stayed the same the correspondence information regarding this application should be directed to Examiner MacFarlane as indicated below.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 7, 2008 has been entered.

Response to Amendment

3. Claims 1, 9 and 105 have been amended, claims 106-112 are newly added, as requested in the amendment filed on March 7, 2008. Following the amendment, claims 1, 5-7, 9, 11-14, 16-19 and 105-112 are pending in the instant application and are under examination in the instant office action.

4. Applicant's arguments filed March 7, 2008 have been fully considered but they are not persuasive for reasons as indicated below.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 11, 13 17, 19 and 105 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 11 is vague and indefinite in its recitation of a "hemodynamically active compound". This term is appears to be novel, and there is no explicit definition of a "hemodynamically active compound" within the instant disclosure. Without a reference to a precise compound one cannot determine the metes and bounds of the claim. Moreover, because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "hemodynamically active compound", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation.

6. The term "facilitates" in claim 13 is a relative term which renders the claim indefinite. The term "facilitates" is not defined by the claim, which neither provide a standard for ascertaining the requisite degree of facilitation nor describes a control agent that does not facilitate blood brain barrier (BBB) passage. Thus, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claims 17 and 19 both recite the limitation "the hematopoietic factor" in Claim 1. There is insufficient antecedent basis for this limitation in the parent claim.

Art Unit: 1649

8. Claim 18 is vague and indefinite in its recitation of the method of Claim 1 "wherein the mammal is human". Claim 1 has reference to mammals twice, therefore it is unclear if the limitation of Claim 18 is intended to limit the mammal to which the compound is administered, or if it is intended to limit the mammal from which the G-CSF is derived.

9. Claim 105 is indecipherable in its recitation of "via stimulation of adult neuronal stem cells". It is unclear if the traumatic injury of the claims occurs via adult NSC stimulation, or if the step of administering the agent occurs via stimulation of adult NSCs. Furthermore, if the latter is the case, the claim appears to be missing essential method steps or critical elements whereby "stimulation" of cells leads to administration of the claimed compound(s). One of ordinary skill in the art would not be reasonably apprised as to the metes and bounds of the claim, and it raises potential issues under the requirement for enablement, as to how a skilled artisan would perform the method.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 9, 18 and 106-108 rejected under 35 U.S.C. 102(b) as being anticipated by Heard *et al.*, *Critical Care Medicine*, 26(4): 748-754, published April 1998 (cited as reference "AZ" on the IDS filed March 19, 2004), as evidenced by NCBI protein

Art Unit: 1649

accession number P09919, the amino acid sequence for Filgrastim, published July 1, 1989.

12. Claim 1 is drawn to a method of treating traumatic brain injury (TBI) in a mammal comprising administering, *inter alia*, one of the following: mammalian G-CSF, human G-CSF, or a protein having at least 90% homology to SEQ ID NO: 28 (which the Sequence listing discloses as human G-CSF). Dependent claims recite the method of Claim 1 wherein human G-CSF is administered (Claim 9); wherein the mammal is human (Claim 18); the method comprising administering mammalian G-CSF (Claim 106); comprising administering a protein having at least 90% homology to SEQ ID NO: 28 and G-CSF activity; comprising administering a protein having at least 95% homology to SEQ ID NO: 28 and G-CSF activity.

13. The Heard et al. prior art teaches a method for the treatment of traumatic brain injury comprising administering recombinant human G-CSF (brand name Filgrastim) to human patients. The NCBI report indicates that the amino acid sequence for Filgrastim is 100% identical to that of SEQ ID NO: 28 of the instant claims as indicated by the alignment below, in which SEQ ID NO: 28 is Query 1 and Filgrastim is Subject 1. Thus, the G-CSF administered by Heard et al. teaches the G-CSF protein of claims 1, 9 and 106-108. Furthermore, the method as taught by Heard et al. teaches administration to humans as required by instant Claim 18. Thus, the reference teaches the method of the instant claims.

Score = 414 bits (1065), Expect = 2e-114

Identities = 207/207 (100%), Positives = 207/207 (100%), Gaps = 0/207 (0%)

Query 1 MAGPATQSPMKLMALQLLLWHSALWTVQEATPLGPASSLPQSFLKCLEQVRKIQGDGAA 60
MAGPATQSPMKLMALQLLLWHSALWTVQEATPLGPASSLPQSFLKCLEQVRKIQGDGAA

Art Unit: 1649

Sbjct	1	MAGPATQSPMKLMALQLLLWHSALWTVQEATPLGPASSLPQSFLLKCLEQVRKIQGDGAA	60
Query	61	LQEKLVSSECATYKLCHEPEELVLLGHSLGIPWAPLSSCPSQALQLAGCLSQLHSGFLYQG	120
		LQEKLVSSECATYKLCHEPEELVLLGHSLGIPWAPLSSCPSQALQLAGCLSQLHSGFLYQG	
Sbjct	61	LQEKLVSSECATYKLCHEPEELVLLGHSLGIPWAPLSSCPSQALQLAGCLSQLHSGFLYQG	120
Query	121	LLQALEGISPELGPTLDTLQLDVADFATTIWQQMEELGMAPALQPTQGAMPAFASAFQRR	180
		LLQALEGISPELGPTLDTLQLDVADFATTIWQQMEELGMAPALQPTQGAMPAFASAFQRR	
Sbjct	121	LLQALEGISPELGPTLDTLQLDVADFATTIWQQMEELGMAPALQPTQGAMPAFASAFQRR	180
Query	181	AGGVLVASHLQSFLEVSYRVLRLHAQP	207
		AGGVLVASHLQSFLEVSYRVLRLHAQP	
Sbjct	181	AGGVLVASHLQSFLEVSYRVLRLHAQP	207

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of Brines et al. *PNAS, USA*, 97(19): 10526-10531, published September 12, 2000.

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100%

Art Unit: 1649

identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising administering one or more additional hematopoietic factors, nor specifically erythropoietin as required by instant claims 5, 6, and 7.

The Brine et al. reference, however, teaches that methods for the treatment of traumatic brain injury comprising administering erythropoietin were well-known in the art prior to filing. Section 2144.06 of the MPEP provides guidance as to obviousness of art recognized equivalence for the same purpose. The court has stated, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The *Kerkhoven* case law is relevant to the instant application because the Heard reference teaches that administration of G-CSF is useful for the treatment of traumatic brain injury and the Brine reference teaches erythropoietin is also useful for the treatment of traumatic brain injury. Thus, it would have been obvious to one of ordinary skill in the art to administer the two compositions in combination. A skilled artisan would be motivated to combine because each composition is useful for the very same purpose, treatment of traumatic brain injury within a mammal.

Art Unit: 1649

17. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of Deleuze et al., *Intensive care Medicine*, 26:1579-1580, published October 2000.

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising administering tissue plasminogen activator as required by instant claim 12. The Deleuze reference, however, teaches that prior to filing method for the treatment of traumatic brain injury comprising administration of tissue plasminogen activator were known in the art. Specifically, Deleuze et al. teach administration of recombinant tissue plasminogen activator to a human patient for the treatment of traumatic brain injury following a pedestrian-motor vehicle accident. For similar reasons as stated above in section 14, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, treatment of humans having traumatic brain injury, in order to form a third composition to be used for the very same purpose. The courts have stated, "[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference.

Art Unit: 1649

18. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of Morita-Fujimura et al. *Journal of Cerebral Blood Flow and Metabolism*, 19(6): 634-642, published June 1999.

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising an anti-apoptotic agent as required by instant claim 14. The instant specification defines anti-apoptotic agents as "e.g. inhibitors of caspases" (paragraph 0072 of PGPub). However, Morita-Fujimura et al. teach the administration of inhibitors of caspases, namely inhibitors of the Interleukin-1beta converting enzyme protease inhibitor "z-VAD.FMK", for the treatment of traumatic brain injury in mammals. As stated above and for similar reasons as stated above in section 14 above, it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, treatment of mammals having traumatic brain injury, in order to form a third composition to be used for the very same purpose. The courts have stated, "[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference.

Art Unit: 1649

19. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of Brines et al. (*Id*) and Deleuze et al. (*Id*).

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising administering both erythropoietin and tissue plasminogen activator as required by instant claim 16. However, since each of the elements are taught by the prior art to be useful for the same purpose of treating traumatic brain injury, then it is *prima facie* obvious to combine the elements into a single composition. Furthermore, In *KSR International Co. v. Teleflex, Inc.*, the Supreme Court has stated that combining prior art elements according to known methods to yield predictable results is *prima facie* obvious if the following rationale can be applied:

(1) the prior art includes each element claimed though not necessarily in the same reference.

(2) it was within the technical grasp of one of ordinary skill in the art to combine the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.

(3) one of ordinary skill in the art would have recognized that the results of such combination were predictable.

(*KSR International Co. v. Teleflex, Inc.* 127 S. Ct. 1727, 82 USPQ2d 1385, Supreme Court, April 30, 2007).

Art Unit: 1649

One of ordinary skill in the art would recognize the use of G-CSF, as taught by Heard et al., in combination with erythropoietin and tissue plasminogen activator, as taught by Brine et al. and Deleuze et al., respectively. A skilled artisan would be motivated to combine the prior art elements because combination would result in the predictable result of treatment of traumatic brain injury. Based on the guidance and direction within the prior art, such combination would have been well within the technical grasp of a skilled artisan. Since each of the elements in combination are merely performing the same function as they did separately, then one of ordinary skill in the art would have been able to predictably combine the elements with a reasonable expectation of success. Therefore, the invention as a whole is *prima facie obvious*, if not actually anticipated by the reference.

20. Claims 109 and 110 rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of Curran and Goa, Drugs 62(8): 1207-1213, May 15, 2002.

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF (brand name filgrastim) that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising administering a mammalian (human) G-CSF comprising one or more chemical substituents as required by instant claims 109 and 110. The Curran and Goa reference, however,

Art Unit: 1649

teach that, prior to filing, pegylated filgrastim was known in the art as a substitute for the filgrastim used in the Heard reference. Curran and Goa teach that this chemically substituted version of filgrastim increases the half-life and decreases serum clearance of the drug in patients (abstract). It would be obvious to one of ordinary skill in the art to use the method for treatment of traumatic brain injury as taught by Heard et al. with the human G-CSF comprising a chemical substituent, namely monomethoxypolyethylene glycol (PEG), as taught by Curran and Goa. A skilled artisan would be motivated to combine because the pegfilgrastim conveys the distinct advantage of increased half-life and decreased clearance in human patients.

21. Claims 111 and 112 rejected under 35 U.S.C. 103(a) as being unpatentable over Heard et al. as applied to claims 1, 9, 18 and 106-108 above, and further in view of MacVittie et al., *Blood*, 95(3):837-845, published February 1, 2000.

The Heard et al. prior art teaches a method for the treatment of traumatic brain injury in mammals comprising administering recombinant human G-CSF (brand name filgrastim) that is 100% identical to that of SEQ ID NO: 28 of the instant claims to human patients suffering from traumatic brain injury.

The Heard reference does not teach the method further comprising administering a mammalian (human) G-CSF fused to a second protein as required by instant claims 111 and 112. The MacVittie et al., reference, however, teaches that chimeric IL-3/G-CSF fusion proteins, termed Myelopoietins in the art, were known as substitutes for G-CSF prior to filing. The MacVittie et al. reference teaches that these Myelopoietins

Art Unit: 1649

display a more favorable pharmacodynamic profile than G-CSF alone and significantly improves the hematopoietic parameters over G-CSF (page 843, Discussion, paragraphs 1-2). It would be obvious to one of ordinary skill in the art to use the method for treatment of traumatic brain injury as taught by Heard et al. with the human G-CSF comprising fusion protein, namely Myelopoietins, as taught by MacVittie et al. A skilled artisan would be motivated to combine because the IL-3/G-CSF fusion protein conveys the distinct advantage of a more favorable pharmacodynamic profile than G-CSF alone and significantly improve the hematopoietic parameters as demonstrated in mammals.

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1649

23. Claims 1, 5-7, 9, 11-14, 16-19 and 105-112 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 9-22 and 52-53 of copending Application No. 10/880,101. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record, as applied to claims 1-19, 101-102 and 105, in the Paper mailed 1/19/2007.

Briefly, both cases the claims are drawn to the same scope of invention, namely, a method of treating a neurological condition in a mammal, comprising administering to the mammal a hematopoietic factor selected from the group consisting GCSF and derivatives thereof, in an amount sufficient to treat the neurological conditions selected from the group consisting of a neurological disease with pathophysiological mechanisms involving ischemia, a neurological disease with pathophysiological mechanisms involving hypoxia, a neurodegenerative disease, and a disease of the nervous system accompanied by neural cell death, wherein the neurological disease with pathophysiological mechanisms involving ischemia or hypoxia is stroke, Parkinson's disease, amyotrophic lateral sclerosis, neurotrauma, cerebral ischemia due to cardiac arrest, or cerebral ischemia during an operative procedure. Dependent claims are drawn to the method further comprising administering one or more additional hematopoietic factors, wherein the hematopoietic factors is erythropoietin; further comprising administering a hemodynamically active compound; further comprising administering tPA; further comprising administering an agent that facilitates passage over the blood brain barrier; further comprising administering an anti-apoptotic agent;

Art Unit: 1649

wherein the hematopoietic factor is a human factor or derived from a human factor;
wherein the mammal is human; wherein the hematopoietic factor is administered by one or more modes of administration selected from the group consisting of direct intracerebral injection, intravenously, intraarterially, orally, and subcutaneously; a method of enhancing the viability of a neural cell culture comprising contacting the neural stem cell hematopoietic factor selected of GCSF or a GCSF derivative. The scope of the claims of each application overlap and are not patentably distinct.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

24. No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M,W and ALT F 7 am to 3:30, T & R 5:30 -5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1649

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649